EXHIBIT E

Crystal Kettenbeil

From:

Eric Stubenvoll

Sent:

Friday, August 22, 2008 1:41 PM

To:

Crystal Kettenbeil

Subject:

FW: Cahill- Supplemental Discovery Responses

Attachments: Cahill- Suppl Ans to Pltf_s Rogs.PDF; Cahill- Suppl Ans to Pltf_s RFP.PDF; Cahill Suppl Doc

Prod-MedWatch Reports.PDF; Cahill-COS for suppl discovery.PDF

From: Nicole Young-Kuykendall [mailto:nkuykendall@smbtrials.com]

Sent: Friday, August 15, 2008 3:12 PM

To: Eric Stubenvoll

Cc: Kay Schichtel; Anthony Monaco

Subject: Cahill- Supplemental Discovery Responses

Eric.

Please find attached Smith & Nephew's Supplemental Answers to Plaintiff's Discovery and responsive documents. A copy will be sent via US Mail as well.

Yours truly, Nicole

Nicole M. Young-Kuykendall, Esq. Swanson, Martin & Bell, LLP 330 N. Wabash, Suite 3300 Chicago, Illinois 60611 (312) 321-8461 - Direct (312) 321-9100 - Main (312) 321-0990 - Fax

nkuykendall@smbtrials.com

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MARY THERESA CAHILL	' ,)	
	Plaintiff,)	
VS.)	No. 08 C 255
SMITH & NEPHEW, INC.,)	District Judge Darrah
	Defendants.))	Magistrate Brown

PROOF OF SERVICE

I, Nicole M. Young-Kuykendall, an attorney, hereby certify that on August 15, 2008, I served Smith & Nephew, Inc.'s Supplemental Answers to Plaintiff's First Set of Interrogatories and Supplemental Responses to Plaintiff's First Request For production via e-mail and regular U.S. Mail to the following:

Eric D. Stubenvoll Fisher Kanaris, P.C. 200 South Wacker Drive, 22nd Floor Chicago, Illinois 60606 (312) 474-1413/(312) 474-1410 FAX ATTORNEY FOR PLAINTIFF

Respectfully submitted,

Kay L. Schichtel ARDC #2480417 Anthony J. Monaco, ARDC #6279545 Swanson, Martin & Bell, LLP 330 N. Wabash, Ste. 3300 Chicago, IL 60611 (312) 321-9100 (312) 321-0990 FAX amonaco@smbtrials.com

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MARY THERESA CAHILL	' 9)	
	Plaintiff,)	
vs.)	No. 08 C 255
SMITH & NEPHEW, INC.,)	District Judge Darrah
	Defendants.)	Magistrate Brown

SMITH & NEPHEW, INC.'S SUPPLEMENTAL ANSWERS TO PLAINTIFF'S FIRST SET OF INTERROGATORIES

Smith & Nephew, Inc. supplements its answers Plaintiff's first set of interrogatories as follows:

INTERROGATORIES

1. Identify each person who assisted in preparing the answers to these interrogatories and, following the identity of each such person, state the number of each interrogatory for which that person provided assistance.

ANSWER: Objection on the grounds that the interrogatory is overbroad and unduly burdensome. Without waiving this objection and by way of response, Smith & Nephew, Inc. states that it is a corporate defendant. As such, these responses were not "answered" by any one person. These responses were prepared by Smith & Nephew, Inc. with the assistance of retained counsel. Dennis Watson, Assistant Secretary, has signed these responses on behalf of Smith & Nephew, Inc.

2. State whether or not this defendant is being sued in its full and correct name. If not, state the full and correct name of this defendant.

ANSWER: Defendant is being sued in its full and correct name.

3. Do you have any statements from any witnesses? If so, give the name, present or

last known address, telephone number, job title, employer, of each such witness, the date of the statement and whether the statement was written or oral.

ANSWER: None other than those produced and supplied by plaintiff or subpoenaed with notice to all parties.

- 4. State whether there exists photographs of the hip prosthetic referenced in the Complaint. If so, state the following:
 - (a) Describe each photograph;
 - (b) State the date each was taken;
 - (c) State the name and address of the person taking each such photo

ANSWER: See enclosed 11 photographs.

- 5. State whether or not any insurance company (including any company with excess or umbrella coverage) has an interest in the outcome of this litigation against defendant. If so, state the following:
 - (a) The name of the insurance company;
 - (b) Whether the insurance company is a stock company or a mutual company;
 - (c) Name of the insured:
 - (d) Type(s) of insurance;
 - (e) Effective policy period;
 - (f) Policy number; and
 - (g) Limits of the policy applicable to the occurrence mentioned in these pleadings.

ANSWER: Smith & Nephew, Inc. is self-insured in an amount sufficient to cover any potential liability in this matter.

- 6. Please state whether you were the manufacturer of the hip prosthetic referenced in plaintiffs Complaint, and if so, please state:
 - (a) The date upon which the subject product was manufactured;
 - (b) The address of the factory and/or such other place at which the subject product was manufactured;
 - (c) Whether, at the time of the manufacturer of the subject product, you had a quality control department and/or individual, or a department

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- and/or individual denominated by a different name which was primarily responsible for quality control procedures for the subject product; and
- If your answer to the foregoing subpart was in the affirmative, the (d) identity of the supervisor and/or person primarily responsible for implementing the quality control procedures, if any, with respect to the subject product.

ANSWER: Smith & Nephew, Inc. manufactured the hip prosthetic referenced in plaintiffs Complaint.

- (a) April 2002.
- Objection. Relevance. Notwithstanding this objection, Tennessee. (b)
- Objection. Whether Smith & Nephew currently maintains a quality (c) control department or division is of no relevance to any issue in this case. Moreover, the request is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. Notwithstanding this objection, see Manufacturing Records.
- See (c) above. (d)
- Please identify any and all production specifications formulated and/or utilized by 7. you in the manufacturing of the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: See Manufacturing Records, 510K, and Print.

Please identify each person who had a responsibility to oversee or supervise the 8. manufacturing of the hip prosthetic referenced in plaintiff's Complaint.

Objection. "Each person who had a responsibility to oversee or supervise the manufacturing of the hip prosthetic referenced in plaintiff's Complaint" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant.

9. Please state whether you designed the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: Smith & Nephew, Inc. designed the hip prosthetic referenced in plaintiff's Complaint.

- 10. If your answer to the foregoing interrogatory is affirmative, please identify:
 - (a) The date or dates upon which the subject product was designed;
 - (b) The location of the facility where the subject product was designed:
 - The name(s) of the person(s) who participated in the design; (c)
 - (d) An identification of each and every drawing, plan, or document relating to the design of the subject product;
 - Whether any such document, plan or drawing identified in your answer to (e) subparagraph (d) has been submitted to any governmental entity for approval, registration, or patent, and if so, the date of said submission and entity to which such document was submitted.

ANSWER:

- See Print. (a)
- (b) See Print.
- (c) Objection. "Name(s) of the person(s) who participated in the design" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant;
- See Print: (d)
- See 510K. (e)
- 11. Do you contend that the retailer who supplied the hip prosthetic referenced in plaintiff's Complaint was aware of any alleged defect in such product?

ANSWER: The subject product was not supplied by a retailer.

- 12. If your answer to the foregoing interrogatory is in the affirmative, please identify:
 - (a) Each and every fact upon which you base such contention;
 - (b) The name, business and residence address, and telephone number of any person having knowledge of any such facts; and
 - An identification of each and every writing relating to any such fact. (c)

ANSWER: See answer to No. 11 above.

13. Please state whether you provided any written instructions or warnings as to the use or installation of the hip prosthetic referenced in plaintiff's Complaint.

Objection. The terms "use or installation" are vague and improper when ANSWER:

used in the context of this lawsuit. Notwithstanding this objection, Smith & Nephew, Inc. included the Package Insert when it sold the hip prosthetic referenced in plaintiff's Complaint.

- 14. If your answer to the foregoing interrogatory is in the affirmative, please identify:
 - (a) The written instructions or warnings;
 - (b) The name, business and residence address, and telephone number of the person(s) who drafted the wording of said instruction; and
 - (c) Each and every writing relating to the composition of all printed matter distributed with or affixed to the product.

ANSWER:

- (a) See Package Insert;
- (b) Objection. "The name, business and residence address, and telephone number of the person(s) who drafted the wording of said instruction" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant; and the information in the Package Insert.
- (c) Objection. This request is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. See Package Insert.
- 15. Identify any and all complaints, lawsuits, or claims submitted to you relating to the alleged defect(s) of similar makes and models of the hip prosthetic referenced in plaintiffs Complaint.

ANSWER: Objection. This request is not limited to the product involved in this case, not limited to the nature of the allegations in this case, not limited in time or in scope and is extremely overbroad and not reasonably calculated to lead to the discovery of admissible evidence. In addition, the request seeks information protected by the attorney-client privilege and work-product doctrines. Notwithstanding these objections, Smith & Nephew states that it has searched its records for the period of January 1, 2001 through May 2, 2008 and states that it has received no other lawsuits and one other claim alleging a fracture of Echelon Hip Model No. 7130413. The claim involved a patient in Ontario Canada. Notwithstanding these objections, Smith & Nephew provides the attached documents.

16. Please state whether you performed any test, of whatever nature or description, for the purpose of determining whether the hip prosthetic referenced in plaintiffs Complaint met

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reasonable performance expectations for its intended use.

ANSWER: Objection. The term "test" is vague and undefined. In the context of litigation "test" can mean a number of things. Notwithstanding these objections, see Manufacturing Records.

- 17. If your answer to the foregoing interrogatory is affirmative, please identify:
 - (a) A description of each such test conducted by you:
 - (b) The date and location where each test was conducted;
 - (c) Whether any aspect of any such test was recorded or memorialized or any document or writing, including photographs, films, videotapes or other visual representations of whatever nature or description;
 - (d) An identification of any such document or visual representation;
 - (e) Whether the results of any such test(s) were submitted, or referred to in any manner whatsoever, and any document filed with or tendered to any public entity or regulatory agency; and,
 - (f) The name, business and residence address, and telephone number of the person(s) charged with the responsibility to evaluate the performance of the subject product in each such test referred to in your answers to the proceeding subparts of this interrogatory.

ANSWER: See No. 16 above.

18. Identify any facts known to you indicating that the hip prosthetic referenced in plaintiffs Complaint had been altered or modified between the time it left the manufacturer's custody and the time it was implanted.

ANSWER: None known at this time. Discovery is on-going. Investigation continues.

19. Identify any facts or circumstances known to you indicating that plaintiff was not using the hip prosthetic referenced in plaintiffs Complaint in a manner reasonably anticipated.

ANSWER: Unknown at this time. Discovery is on-going. Investigation continues.

20. State the name of each expert witness that you expect to testify at the trial of your

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claims in this case, and for each such witness provide the following:

The subject matter on which the witness will testify; (a)

The conclusions and opinions of the witness, and the bases therefore; (b)

The qualifications of the witness; (c)

Any report prepared by the witness about the case; (d)

Any exhibits to be used as a summary of or support for the opinions; (e)

- The compensation to be paid in relation to the witness's testimony and preparation (f) therefore: and
- A list of any other cases in which the witness has testified as an expert at (g) trial or by deposition within the last four years.

Unknown at this time. Defendant will disclose its experts in accordance ANSWER: with the court's scheduling order.

State the names and addresses of all fact witnesses you expect to call at the trial of 21. your claims in this case and state what you expect to be the substance of each witness' testimony.

ANSWER: Unknown at this time. Defendant's first notice of this claim was upon service of the complaint. Defendant expects that any witnesses to the incident may be called to testify. The identity of those witnesses is in the exclusive control of the plaintiff. In addition, defendant anticipates that plaintiff's treating physicians (pre and post incident) may have relevant information. See plaintiff's deposition. At this time, defendant is unsure which fact witnesses have relevant information. Once plaintiff produces his final Rule 26 expert report and defendant is apprised of the specific defect claimed, defendant will be in a position to identify all fact witnesses that have relevant information and who may be called to testify at trial. Therefore, defendant expects to supplement this response in the future.

7

Respectfully submitted,

SMITH & NEPHEW, INC.

Kay L. Schichtel Anthony M. Monaco, ARDC 6279545 Nicole M. Young-Kuykendall, ARDC 6294692 Swanson, Martin & Bell, LLP 330 N. Wabash St., Suite 3300 Chicago, IL 60611

(312) 321-9100 (312) 321-0990 FAX

VERIFICATION

Under penalties as provided by law, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that he verily believes the same to be true.

Dennis Watson Assistant Secretary

Smith & Nephew, Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS **EASTERN DIVISION**

MARY THERESA CAHILL,)
Plair	tiff,
vs.) No. 08 C 255
SMITH & NEPHEW, INC.,) District Judge Darrah
Defe	ndants.) Magistrate Brown

SMITH & NEPHEW INC.'S SUPPLEMENTAL RESPONSES TO PLAINTIFF'S FIRST REQUEST FOR PRODUCTION

Smith & Nephew, Inc.'s responds to plaintiff's first request for production as follows:

All documents that evidence, related to, or in any way substantiate your answers to the plaintiff's Interrogatories.

RESPONSE: All documents are identified and produced in response to specific requests.

All non-privileged statements or other writings summarizing or containing statements of any party relating to the incident alleged in the plaintiff's Complaint and/or the injuries and damages allegedly resulting therefrom.

RESPONSE: None other than medical records which were subpoenaed with notice to all parties.

All photographs, slides, motion pictures, models, videotapes, and/or exhibits of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: See 11 photographs enclosed.

All documents related to the manufacturing of the hip prosthetic referenced in plaintiff's Complaint, including but not limited to drawings and specifications.

RESPONSE: Objection. The term "documents" is undefined and overbroad. Notwithstanding this objection, see Manufacturing Records, Print and 510K.

5. All instructions related to the to the hip prosthetic referenced in plaintiff's complaint.

RESPONSE: Objection. The term "instructions" is undefined and overbroad. Notwithstanding this objection, see Package Insert and Surgical Technique.

- 6. Any applicable safety standards or codes considered, governing, or used in the design and/or manufacture of the hip prosthetic referenced in plaintiff's Complaint.
- **RESPONSE**: Objection. This request is overbroad because it is not limited in scope and to the issues in this lawsuit. Notwithstanding these objections, see attached Manufacturing Records, Print, and 510K.
 - 7. All warnings related to the hip prosthetic referenced in plaintiff's Complaint.
- **RESPONSE**: Objection. The term "warnings" is undefined and overbroad. Notwithstanding this objection, see plaintiff's medical records, the Package Insert, and the Surgical Technique.
- 8. Any report prepared by any expert witness about the case, including any exhibits to be used as a summary of or support for the opinions.
- **RESPONSE**: None at this time. Smith & Nephew will supplement this in accordance with the court's scheduling order.
- Any and all documents relating to testing performed by or for defendant related to the hip prosthetic referenced in plaintiff's Complaint including results of any testing or inspection for safety of the product.
- **RESPONSE:** Objection. The term "testing" is undefined and can mean a wide variety of things in litigation and thus, the interrogatory is vague and ambiguous. Notwithstanding this objection, see the Manufacturing Records.
 - All documents reflecting the origin, manufacturer, date of manufacture, and purchaser of the hip prosthetic referenced in plaintiff's Complaint.
 - **RESPONSE**: Objection. The term "origin" is vague and ambiguous. Notwithstanding these objections, see Manufacturing Records.
 - Copies of any and all documents relating to any claim, complaint, report or incident similar to plaintiff's claim as referenced in the Complaint.
 - **RESPONSE**: Objection. This request is not limited to the product involved in this case, not limited to the nature of the allegations in this case, not limited in time or in scope and is extremely overbroad and not reasonably calculated to lead to the discovery of admissible evidence.

In addition, the request seeks information protected by the attorney-client privilege and work-product doctrines. Notwithstanding these objections, Smith & Nephew states that it has searched its records for the period of January 1, 2001 through May 2, 2008 and states that it has received no other lawsuits and one other claim alleging a fracture of Echelon Hip Model No. 7130413. The claim involved a patient in Ontario Canada. Notwithstanding these objections, Smith & Nephew provides the attached documents.

Any and all brochures, manuals, parts lists, instructions, written materials, advertising 12. materials, or other documents relating to the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. This request is overbroad and not limited in time, scope or to the issues raised in this lawsuit. Notwithstanding these objections, see the 6 marketing brochures.

Copies of warranties given to the purchaser(s) of the hip prosthetic referenced in 13. plaintiff's Complaint.

RESPONSE: None.

Any and all documents, records, or tangible evidence that the product was altered or modified between the time it was sold and the date of the Occurrence in question.

RESPONSE: Unknown at this time. Discovery is on-going. Investigation continues.

Any and all documents or records evidencing that this defendant complied with all 15. applicable statutes, regulations, and standards existing at the time of manufacture that prescribed standards for design, inspection, testing, manufacture, labeling, packaging, or instruction for use of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. The terms "documents" and "records" are undefined and overbroad. In addition, this request is not limited to the issues raised in this lawsuit. Notwithstanding these objections, see 510K and Manufacturing Records.

Respectfully submitted,

SMITH & NEPHEW, INC.

Kay L. Schichtel Anthony M. Monaco, ARDC 6279545 Nicole M. Young-Kuykendall, ARDC 6294692 Swanson, Martin & Bell, LLP 330 N. Wabash St., Suite 3300 Chicago, IL 60611

(312) 321-9100 (312) 321-0990 FAX

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VERIFICATION

Under penalties as provided by law, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that he verily believes the same to be true.

Dennis Watson

Assistant Secretary

Smith & Nephew, Inc.

U.S. Department of Health and Human Services Food and Drug Administration Smith & Nephew, Inc., Orthopsedic Division For use by user-facilities. onal Isc., PDA Facelmille Appreval: 4/17/2007 MEDWATCH importers, distributors and manufacturers 1020279-2008-00179 3500A Facsimile for MANDATORY reporting Page 1 of 3 FDA Use C A. PATIENT INFORMATION C. SUSPECT PRODUCT(S) Patient Identifier 2. Age at Time of Even 3. Sex 4. Weight Name (Give labeled strength & mir/labeler, X Female UNK # 1. Date of Birth: 11/20/1930 In confidence UNK # 2. B. ADVERSE EVENT OR PRODUCT PROBLEM 2. Dose, Frequency & Route Used 3. Therapy Dates (If unknown, give duration) from/to (or best estimate) X Adverse Event Product Problem (e.g., defects/mailunctions) # 1 # 1. Outcomes Attributed to Adverse Event (Check all that apply) 62 # 2 4. Diagnosis for Use (Indication) Death Disability or Permenent Damage 5. Event Absted After Use Stopped or Dose Reduced? #1 Life-threatening # 1. Yes Ho Docum Congenital Anomaly/Birth Defect 82 | Hospitalization - initial or prolonged Other Serious (Important Medical Events) 6. Lot # 7. Exp. date # 2. You No # 1. Required intervention to Prevent Permanent Impairment/Damage (Davices) 8. Event Reappeared After Reintroduction? 2 #2. 3. Date of Event (months/yyyy) 4. Date of This Report (ments) 9. NDC# or Unique ID 05/22/2008 #1. Ym | No 06/02/2008 Doesn's Apply # 2. Y** No 5. Describe Event or Problem 10. Composition Medical Products and Therapy Dates (Exclude treatment of event) It was reported that revision surgery was performed after the patient fell resulting in femur fracture and proethesis fracture. D. SUSPECT MEDICAL DEVICE **Echelon** 2. Common Device Name Starn 3. Manufacturer Name, City and State Smith & Nephew Inc., Orthopaedic Div. 1450 Brooks Road Memphis, TN 38116 USA 4 Model # Lot 5. Operator of Device UNK INK X Heelth Profes Catalog Expirat on Date (mm/ddfyyyy) Ley User/Pai 71340812 UNK Same a Other Other NA NA 8. If implersted, Give Date (7. If Explanted, Give De 05/05/2008 6. Relevant Tests/Laboratory Data, Including Dates te (mro/dd/yyyy) 05/22/2007 UNK 8 is this a Single-use Device that Yes X No d and Reused on a Patient? 9. If Yes to Ham No. 8, En er Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) 08/02/2008 Yes □ 140 X Returned to Manufacturer on (mmkldlyyyy) nt Medical Products and Therapy Dates (Exclude Insetm 7. Other Relevant History, including Presideting Medical Conditions (a.g. ellerples, rece, pregnancy, smoking and alcohol use, hepsitorenal dystunction, etc.) UNK E. INITIAL REPORTER 1. Name and Address Phone # 07176577342 Craig Holman, PINNACLE HEALTH SYSTEM PO BOX 8700 HARRISBURG, PA 17105, Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or

2. Health Professional? 3. Occupation

Sales rep

X No

T Yes

contributed to the event.

4. Initial Reporter Also Sent

X Unk

Report to FDA

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Page 3 of 3

Smith & Nephew, I	Inc., Orthopaedic Divisio	n
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ADDITIONAL INFORMATION

U.S. Food and Drug Administration & Headth and Hulling at Section 2.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | CDRH A-Z Index | Contact CDRH



510(k) | Registration & Listing | Adverse Events | PMA | Classification | CLIA CFR Title 21 | Advisory Committees | Assembler | Recalls | Guidance | Standards

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71341113 Event Date 05/16/2008

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention **Event Description**

It was reported that revision surgery was performed due to a breakage of the device.

Manufacturer Narrative

Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device FEMORAL STEM

Baseline Device 510(K) Number

Baseline Device PMA Number

Manufacturer (Section F)

SMITH & NEPHEW, INC.,

ORTHOPAEDIC DIV.

1450 Brooks Rd.

Memphis TN 38116

SMITH & NEPHEW, INC.,

Manufacturer (Section D) ORTHOPAEDIC DIV.

1450 Brooks Rd.

Memphis TN 38116

SMITH & NEPHEW, INC.

Manufacturer (Section G) 1450 Brooks Rd.

Memphis TN 38116

Melanie Travis

Manufacturer Contact 1450 Brooks Rd.

Memphis, TN 38116

(901) 399 -6233

Device Event Key 1029765

MDR Report Key 1060210

Event Key 1018279

Report Number 1020279-2008-00178

Device Sequence Number 1

Product Code KWY

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 06/16/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 06/16/2008

Is This An Adverse Event Report? Yes

is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71341113

Device LOT Number 06DM01764

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No.

Date Manufacturer Received 05/27/2008

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Date Device Manufactured 04/01/2006

Is The Device Single Use? Yes

Is this a Reprocessed and Reused Single-Use

Device? IN

Is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON POROUS STEM

back to search results

Catalog Number 71340111

Event Date 05/05/2008

Event Type Injury Patient Outcome Hospitalization; Required Intervention Manufacturer Narrative
Na.

Event Description

It was reported that revision surgery was performed due to a fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device POROUS STEM

Baseline Device 510(K) Number
Baseline Device PMA Number

SMITH & NEPHEW, INC.,

Manufacturer (Section F) ORTHOPAEDIC DIV. 1450 Brooks Rd.

Memphis TN 38116

SMITH & NEPHEW, INC.,

Manufacturer (Section D) ORTHOPAEDIC DIV.

1450 Brooks Rd. Memphis TN 38116

SMITH & NEPHEW, INC.,

Manufacturer (Section G) ORTHOPAEDIC DIV 1450 Brooks Rd.

Memphis TN 38116

Scott English

Manufacturer Contact 1450 Brooks Rd. Memphis, TN 38116

(901) 399 - 5989

Device Event Key 1022034

MDR Report Key 1052807

Event Key 1010958

Report Number 1020279-2008-00163

Device Sequence Number 1

Product Code KWY

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 05/27/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 05/27/2008

is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340111

Device LOT Number 06GM01277

Was Device Available For Evaluation? No

is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Date Manufacturer Received 05/16/2008

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Date Device Manufactured 07/01/2006

Is The Device Single Use? Yes Is this a Reprocessed and Reused Single-Use No

Device?

Is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Initial

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON STEM

back to search results

Page 27 of 42

Catalog Number 71340117 Event Date 04/11/2008 Event Type Malfunction Patient Outcome Required Intervention; Manufacturer Narrative Na.

Event Description

It was reported that device was undersized, and did not function as intended, the surgeon performed add'l reaming of the pts bone to achieve a proper fit.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device STEM

Baseline Device 510(K) Number **Baseline Device PMA Number**

SMITH & NEPHEW, INC.,

ORTHOPAEDIC DIV. Manufacturer (Section F)

1450 Brooks Rd. Memphis TN 38116

SMITH & NEPHEW, INC.,

ORTHOPAEDIC DIV. Manufacturer (Section D)

1450 Brooks Rd. Memphis TN 38116

SMITH & NEPHEW, INC.

Manufacturer (Section G) 1450 Brooks Rd.

Memphis TN 38116

Melanie Travis 1450 Brooks Rd.

Manufacturer Contact Memphis, TN 38116

(901) 399 -6233

Device Event Key 1041160

MDR Report Key 1046223

Event Key 1004420

Report Number 1020279-2008-00149

Device Sequence Number 1

Product Code KWY

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 05/09/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 05/12/2008

is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator Health Professional

Device Catalogue Number 71340117

Device LOT Number 05FM01493

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 04/17/2008

is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Date Manufacturer Received 04/14/2008

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 06/01/2005

Is The Device Single Use? Yes

is this a Reprocessed and Reused Single-Use Device?

Is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Initial

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON STEM

back to search results

Catalog Number 71340117 **Event Date 03/09/2005** Event Type Injury Patient Outcome Hospitalization; Required Intervention Manufacturer Narrative Na.

Event Description

It was reported that revision surgery was perform due to dislocation.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device STEM

Baseline Device 510(K) Number **Baseline Device PMA Number**

SMITH & NEPHEW, INC.,

Manufacturer (Section F)

ORTHOPAEDIC DIV. 1450 Brooks Rd.

Memphis TN 38116

Manufacturer (Section D)

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.

1450 Brooks Rd. Memphis TN 38116

Manufacturer (Section G)

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.

1450 Brooks Rd. Memphis TN 38116

Melanie Travis

Manufacturer Contact

1450 Brooks Rd. Memphis, TN 38116 (901) 399 -6233

Device Event Key 985589

MDR Report Key 1017335

Event Key 976101

Report Number 1020279-2008-00095

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 03/20/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 03/24/2008

is This An Adverse Event Report? Yes

is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340117

Device LOT Number 81101075

Is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Date Manufacturer Received 03/06/2008

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Is The Device Single Use? Yes

is this a Reprocessed and Reused Single-Use
Device?

is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

U.S. Department of Health and Human Services Food and Drug Administration Sn

Smith & Nephew, Inc., Orthopsedic Division

MEDWATCH 3500A Faceimile For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

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	1020279-2008-00092

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B. ADVERSE EVENT OR I	RODUCT PROBLEM				
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2. Outcomes Attributed to Adverse Event	Product Problem (e.g., defects/matturictions)) #1		# 1.	asi aspimate)
(Check ell that apply)		# 2.			
☐ Seath	Dissbility or Permanent Damage	4. Diagnosia for	Use (Indication)	82.	
Life-threatening		# 1.	(Messale)	5. Eve	nt Abated After Use
X Hospitalization - initial or prolonged	Congenital Anomaly/Birth Defect	N 2,			ped or Dose Reduced?
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Date of Every immunity	rmansni impairment/Damage (Devices)	₩ 1.	# 1,	* 2. <u>[</u>	Yes No Doubly
	4. Date of This Report (ministry)	#2.	# 2.	8. Eve Rei	1 Responsed After Production?
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Describe Event or Problem	<u></u>			# 2. T	
(was reported that revision suge	ery was performed due to breakage o	10. Comcomitant	Medical Products and The	rapy Dates (Exclude in	Appy Appy
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		1. Name and Address	Phone	£ 001 202 co-	<u> </u>
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		SMITH & NEPHEW 1450 BROOKS ROA	ORTHO SPECIALTIES	3	7
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				Device Evaluation
4. Contact Person	*·		Device Evaluated by Manufacturer? Not Returned to Manufacturer	4. Device Manufacture Date (mm/yyyy)
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Report Sent to FD/	12.	Location Where Event Occurred	7. If Remedial Action Initiated, Chack Type	18. Usage of Device
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10903 New Hampehire Avenue Building 22, Meil Stop 4447 Sever Spring, MD 20003-0002 Please DO NOT RETURN this form to this address

and a person is not required to response to a collection of information unless it displays a currently valid OMB control remarks."

MEDWATOR		Smith & Nephew, Inc., Orthopaedic Division
3500A Facsimile (Back) - (continued)	From 3 of 3	Unimpertor Report o 1020279-2008-00092
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Adverse Event Report SMITH & NEPHEW, INC. ECHELON STEM

back to search results

Catalog Number 71340514

Event Type Injury Patient Outcome Hospitalization; Required Intervention **Event Description**

It was reported that revision surgery was performed due to a fracture of the device.

Manufacturer Narrative Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device STEM

Baseline Device 510(K) Number **Baseline Device PMA Number**

> SMITH & NEPHEW, INC. Manufacturer (Section F) 1450 Brooks Rd.

Memphis TN 38116

SMITH & NEPHEW, INC. Manufacturer (Section D) 1450 Brooks Rd.

Memphis TN 38116

SMITH & NEPHEW, INC.

Manufacturer (Section G) 1450 Brooks Rd.

Memphis TN 38116

Melanie Travis, Reg Compliance

1450 Brooks Rd **Manufacturer Contact** Memphis, TN 38116

(901) 399 -6233

Device Event Key 942788

MDR Report Key 973024

Event Key 933607

Report Number 1020279-2008-00001

Device Sequence Number 1

Product Code KWY

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 01/02/2008

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 01/03/2008

is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340514

Device LOT Number 01AM14333

Was Device Available For Evaluation? No

is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Date Manufacturer Received 12/04/2007

Was Device Evaluated By Manufacturer? Device Not Returned To

Manufacturer

Date Device Manufactured 01/01/2001

Is The Device Single Use? No

Is this a Reprocessed and Reused Single-Use
Device?

is the Device an implant? No

is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008



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Adverse Event Report

SMITH & NEPHEW, INC.,/ ORTHOPAEDIC DIV. ECHELON STEM

back to search results

Catalog Number 71340415 **Event Date 08/17/2007** Event Type Injury Patient Outcome Hospitalization; Required Intervention **Manufacturer Narrative** Na.

Event Description

It was reported that revision surgery was performed due to a fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name ECHELON

Type of Device STEM

Baseline Device 510(K) Number **Baseline Device PMA Number**

Manufacturer (Section F)

SMITH & NEPHEW, INC./

ORTHOPAEDIC DIV.

1450 Brooks Road Memphis TN 38116

SMITH & NEPHEW, INC.,/

Manufacturer (Section D)

ORTHOPAEDIC DIV. 1450 Brooks Road

Memphis TN 38116

SMITH & NEPHEW, INC. Manufacturer (Section G) 1450 Brooks Road

Memphis TN 38116

Manufacturer Contact

Melanie Travis. 1450 Brooks Road Memphis, TN 38116

(901) 399 -6233

Device Event Key 887982

MDR Report Key 912475

Event Key 874708

Report Number 1020279-2007-00220

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 08/15/2007

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 09/14/2007

Is This An Adverse Event Report? Yes

is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340415

Device LOT Number 00805321

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 08/21/2007

is The Reporter A Health Professional? No

Was The Report Sent To Manufacturer? No

Date Manufacturer Received 08/15/2007

Was Device Evaluated By Manufacturer? Yes

Is The Device Single Use? Yes

Is this a Reprocessed and Reused Single-Use
Device?

is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

Filed 08/22/2008

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Center for Devices and Radiological Health / CDRH

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

V.S. Department of Hea Food and Drug Admini	ith and Hum stration		£ bioshour to	Ombossati	<i>(</i> 0, ¢ . • . •								
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4				e 1 of 3		····	FDA Uso						
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				2. Common Device Stern 3. Menufacturer Nar Smith & Nephew 1450 Brooks Ros Memphis, TN 38: 4. Model # NA Cstalog # 71340112 Serial # NA 6. If Implanted, Give	Inc., Orthopaedic Div. d 116 USA Lot # 00504577A Expiration Date UNK Other # NA	(mm/8d/yyyy)	5. Operator of Device XiHealth Professional Lay User/Patient Other:						
6. Relevant Tests/Leboratory Date, I) UN	K	07/12/20							
It has been implanted appro	ximately 4 1/	'2 yrs before break	age.	9. If Yes to item No. 10. Device Available Yes N	8, Enier Name and Addre	ess of Reprocessor end to FDA) Asnutacturer on	07/18/2007 /mm/ht/bassi						
Other Relevant Minimum Institute	enviation Africa	al Condition of the Condition		11. Concomitant Medi UNK	ical Products and Therep	y Detes (Exclude tres	ment of event)						
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			***************************************	Scott Strzelecki, WATERBURY HOS 64 ROBBINS ST	l Hao	ne \$ 203 573 6000)						
				WATERBURY, CT	08708, USA								

2. Health Professional? 3. Occupation

4. initial Reporter Also Sent

Report to FDA

Yes The Turk.

Smith & Nephew, Inc., Orthopsedic Division

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1.Contact Office - Name		200	no Silia kar i	Davicest	2. Phone Nu	mber											
Mrs. Melanie Tra	zvis, Reg	Complian	nce	-		99-6233											
Smith & Nephew 1450 Brooks Roo	v, Inc., O	rthopaedic	: Divisi	ดก]										
Memphis, TN 38		Ą			3. Report So (Check all]										
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07/16/200 6. If IND, Give Protocol		ND#			User F	ecility											
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7. Type of Report		PMA/ 510(k) # _		···	Repres	entative											
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The public reporting burden for this collection of information has been estimated to everage 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other sepect.

Copariment of Health and Human Services
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Building 22 Link Stop 6447

		Smith & Nephew, Inc., Orthopaedic Division
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